Opening Statement of Chairman Fred Upton
Health Subcommittee Hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations"
November 17, 2015

(As Prepared for Delivery)

The 21st Century Cures Act passed our committee 51-0 and sailed through the House in July with 344 votes. It was the product of over a year's worth of ideas we received via our numerous white papers, hearings, and dozens of roundtables in Washington, Michigan, and across the country. Provisions were proposed and thoroughly scrutinized with the help of a wide variety of stakeholders, in and out of government, and of all political stripes. It goes without saying that for any piece of meaningful legislation to garner broad support, finding areas of common ground is critical. In our good faith effort, some important pieces of the puzzle didn't get included because the timing just wasn't right. Modernizing our regulatory framework for the review and oversight of diagnostics is one of those pieces, and I look forward to moving the ball forward on that conversation today.

As I said at our first forum on this topic in July 2014, these increasingly important and complex tests are providing researchers and clinicians with valuable tools to match the right patients with the right treatments. We must ensure that our laws and regulations keep pace so that innovation in this space continues and patients benefit from accurate and reliable tests.

I saw 21st Century Cures as a unique opportunity to elicit feedback on what such a framework should look like and what role Congress could play in developing it. We issued a white paper asking targeted questions and were impressed with the scope and thoroughness of the responses we received. We realized early on that the traditional medical device framework was not ideally suited for these unique tests, which provide clinicians with critical information but do not actually provide therapy to a patient.

It was also apparent that there was quite a difference of opinion about what the roles and responsibilities of FDA and CMS should be. Developing legislative language with broad support on an abbreviated timeframe was not achievable. We opted to table these discussions until we got Cures through the House, and to urge stakeholders to use that time to forge ahead and find as much common ground as possible.

I was very encouraged to hear that a diverse group of stakeholders with different points of view came together and, in the spirit of finding consensus, developed a draft framework that answered a lot of our questions in a responsible and balanced manner. There is always room for improvement, but folks need to be realistic in their approach and pragmatic with their suggestions if the ultimate goal is a bill signed into law any time soon. We must get this right and we need everyone's help in order to do so.